REMARKS

Claims 1-9 are cancelled.

Claims 10 – 24 are pending. Claims 12-14 are withdrawn from consideration.

New Claim

New claim 24 is supported by the specification at, for example, page 30. No new matter is added by way of new claim 24.

Rejections under 35 U.S.C. §112, first paragraph

Claims 10, 11 and 15-23 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner admits that the applicants disclose the structures of peptide molecules having MSH biological function but takes the position that no antagonists of MSH are disclosed.

Applicants respectfully disagree. On pages 30-32 of the specification, Applicants describe numerous exemplary MSH analogs that may be particularly useful as MSH antagonists. On page 27 of the specification, the applicants also incorporate by reference a number of U.S. Patents describing structures and methods of preparation of numerous MSH compounds. One of these patents, U.S. 5,731,408 ("the 408 patent"), reports prior structure-function analysis on the affinity and potency of MSH at the MSH receptor. (See the 408 patent at column 1, lines 47-56.) Reportedly, these studies resulted in the identification of a number of MSH antagonists. The 408 patent also discloses a structural-activity relationship indicating the specificity of antagonist action to a certain chemical structure. (See the 408 patent at column, Table III.)

The structural-functional relationship of MSH ligands has been studied extensively for the past thirty years. These studies have recently been

reviewed by Holder and Haskell-Luevano, "Melanocortin Ligands: 30 Years of Structure-Activity Relationship (SAR) Studies", Medicinal Research Reviews, vol. 24, no. 3, pp. 325056 (2004). A copy of this review is included for the convenience of the Examiner. On pages 333 and 334 of this publication, the authors describe that in 1995, it was known that modification of the Phe7 amino acid of MSH results in antagonist action. Applicants submit that, at the priority date of the present application, MSH antagonists and, in particular the structural characteristics of these molecules, where known to those skilled in the art.

Claims 10, 11 and 15-23 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner bases this position, in part, on his view of the unpredictability of the art and on Lee et al (WO 97/47316) and Klebig et al. (PNAS 92: 4728-4732; 1995). According to the Examiner, Lee and Klebig teach that agouti protein is an antagonist of MSH biological activity and that this protein increases insulin resistance and a form of type II diabetes associated with insulin resistance. Consequently, MSH antagonists are said to be associated with increased obesity and diabetes associated with insulin resistance.

In response, the Applicants enclose a declaration pursuant to 37 CFR §1.132 by Dr. Miles Brennan, an inventor of the present invention, including experimental results showing the effect of a MSH antagonist in reducing glucose levels in hyperglycemic obese (ob/ob) mice. Applicants respectfully submit that these results demonstrate the ability of a MSH antagonist to amerliorate the effects of insulin resistance and diabetes caused by insulin resistance.

Favorable consideration and allowance of this application are respectively requested for the reasons set forth in the above remarks. In particular, for at least the reasons given above, the applicants respectfully request that the Examiner withdraw the rejections of claims 10, 11 and 15-23

under 35 U.S.C. §112, first paragraph. If, for any reason, the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

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